GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2231
ANSWERED ON:29.08.2007
REGULATIONS FOR MEDICAL DEVICES
Tripathy Shri Braja Kishore

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government proposes to regulate medical devices in the country;

(b) if so, the details thereof;

(c) the extent to which such regulations will improve the quality of medical devices in the country; and

(d) the time by which such regulations are likely to be implemented?

Answer

THE MINISTER OF THE STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (DR. ANBUMANI RAMADOSS)

(a)&(b): Yes, 14 Items of Medical Devices have already been included as drugs under the definition of drug in the Drugs & Cosmetics Act, 1940 vide GSR 109(E) dated 22.2.1994, GSR 600 (E) dated 27.08.2002 and GSR 627(E) dated 7.10.2005. Thereby manufacture, sale and import of these items are controlled as per law.Further guidelines for the manufacture and import have been prepared and posted in the website www.cdsco.nic.in

(c): Control of manufacture, sale and import of Medical Devices under law will improve the quality of such devices by curbing unethical manufacturing practices.This will also curb and control devices which are out of specifications/counterfeit.The manufacturers will be benefited by the regulations as proper GMP will be followed by them resulting in good products.

(d): The regulations are already in place.